

FILSPARI™ is a

once-daily treatment

urine (proteinuria) in adults with primary

FILSPARI is not a steroid. It does not suppress your

IgA nephropathy

immune system.

to lower protein in the



DOSING GUIDE for FILSPARI™ Patients

Before starting FILSPARI

Here are some important considerations to keep in mind:

FILSPARI will be provided to you by a specialty pharmacy enrolled in the FILSPARI Risk Evaluation and Mitigation Strategy (REMS) Program. Your doctor will give you complete details.



Tell your doctor about all your medical conditions, including high blood pressure, heart problems, or liver problems. Discuss all the medications you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, grapefruit, and antacids or acid reducers.

Be sure to tell your doctor if you take:

- nonsteroidal anti-inflammatory drugs (NSAIDs)
- potassium-containing medicines, supplements, or salt substitutes
- blood pressure medicines



Learn about the potential risks of FILSPARI. Read about possible side effects in the **Medication Guide**, and go over all your questions together with your doctor.



Understand your responsibilities while on treatment.

All patients must get a liver function test before starting FILSPARI, every month for the first 12 months during treatment, then every 3 months after that while taking FILSPARI.

Patients who can become pregnant must have a negative pregnancy test before starting FILSPARI, every month during treatment, and for 1 month after stopping FILSPARI.

Further information is available at **FILSPARI-REMS.com**, or call 1-833-513-1325.

WHAT IS FILSPARI™ (sparsentan)?

FILSPARI is a prescription medicine to lower protein in the urine (proteinuria) in adults with primary IgA nephropathy who are at risk of their disease quickly getting worse. It is not known if FILSPARI is safe and effective in children.

FILSPARI has been approved based on a reduction of proteinuria. Continued approval may require results from an ongoing study to determine whether FILSPARI slows decline in kidney function.

IMPORTANT SAFETY INFORMATION

FILSPARI is only available through the FILSPARI Risk Evaluation and Mitigation Strategy (REMS) Program because of the **serious risk of liver problems and serious birth defects.** Before you begin taking FILSPARI, you must read and agree to all the instructions in the FILSPARI REMS Program.

FILSPARI can cause changes in liver tests. Some medicines that are like FILSPARI can cause liver failure. Your healthcare provider will do blood tests to check your liver before starting FILSPARI, monthly for the first 12 months, and then every three months during treatment. Your healthcare provider may temporarily stop or permanently stop treatment with FILSPARI if you have changes in your liver tests.

Please see additional Important Safety Information throughout this guide. Please also see the full Prescribing Information, including serious side effects, and the Medication Guide.



Recommended treatment schedule

Take FILSPARI™ exactly as your doctor tells you to take it.



Take the full daily dose of FILSPARI with water before either your morning or evening meal

Whichever meal you choose to dose prior to, maintain that pattern. It's important to make taking FILSPARI something you do consistently, every day.

It is recommended that you begin FILSPARI as follows:

- **Before taking FILSPARI**, you should stop taking any angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren. All patients must get a liver function test. Patients who can become pregnant must also have a negative pregnancy test.
- For the first 14 days (Weeks 1 & 2), take 200 mg once daily
- After 14 days (Week 3 onward), your doctor may increase your dose to 400 mg once daily, depending on how well you tolerate FILSPARI





*If tolerated.

If you miss a dose, take the next dose at the regularly scheduled time. Do not take 2 doses at the same time or take extra doses. Reach out to your Travere TotalCare $^{\text{TM}}$ team for treatment questions and help setting up monthly prescription refills.

Supply and storage

FILSPARI comes in two dosage strengths

Store FILSPARI at room temperature in its original container. Do not refrigerate.



200 mg tablets



400 mg tablets

Not actual size.

IMPORTANT SAFETY INFORMATION (continued)

Tell your healthcare provider right away if you develop any of the following signs of liver problems during treatment with FILSPARI: nausea or vomiting, pain on the upper right side of your stomach area, tiredness, loss of appetite, yellowing of the skin or the whites of your eyes (jaundice), dark "tea-colored" urine, fever, or itching.

FILSPARI can cause serious birth defects if taken during pregnancy. Patients must not be pregnant when they start taking FILSPARI, become pregnant during treatment, or for one month after stopping treatment. Patients who can become pregnant must have a negative pregnancy test before starting FILSPARI, monthly during treatment, and for one month after stopping FILSPARI.

Patients who can become pregnant are those who have entered puberty, even if they have not started their menstrual period, and have a uterus, and have not gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed.

Patients who cannot become pregnant are those who have not yet entered puberty, or do not have a uterus, or have gone through menopause (menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed), or are infertile for any other medical reason and this infertility is permanent and cannot be reversed.

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SUPPORT AND RESOURCES WITH Travere Total Care



Living with a rare disease like IgA nephropathy can be challenging. That's why Travere TotalCare $^{\text{TM}}$ provides support for FILSPARI $^{\text{TM}}$ patients to help throughout the treatment journey.

Dedicated to your care, our team offers personal assistance for those taking FILSPARI. From financial support to delivery of medication, we can help with many aspects of managing your IgA nephropathy.





Learn more about FILSPARI at FILSPARI.com

IMPORTANT SAFETY INFORMATION (continued)

Patients who can become pregnant must use effective birth control during treatment with FILSPARI and for one month after stopping FILSPARI because the medicine may still be in your body.

- If you have had a tubal sterilization or have an IUD (intrauterine device) or progesterone implant, these methods may be used alone, and no other form of birth control is needed.
- Talk with your healthcare provider or gynecologist (a healthcare provider who specializes in reproduction) to find out about options for effective forms of birth control that you may use to prevent pregnancy during treatment with FILSPARI.
- If you decide that you want to change the form of birth control that you use, talk with your healthcare provider or gynecologist to be sure that you choose another effective form of birth control.
- **Do not have unprotected sex.** Talk to your healthcare provider or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your healthcare provider may talk with you about using emergency birth control.
- Tell your healthcare provider right away if you miss a menstrual period or think you may be pregnant.

Do not take FILSPARI if you are pregnant, plan to become pregnant, or become pregnant during treatment. FILSPARI can cause serious birth defects. Do not breastfeed if you are taking FILSPARI.

Do not take FILSPARI if you are taking any of these medicines: an angiotensin receptor blocker, an endothelin receptor antagonist, or aliskiren. Ask your healthcare provider if you are not sure if you take one of these medicines.

Before taking FILSPARI, tell your healthcare provider about all of your medical conditions, including if you have high blood pressure or heart problems, or liver problems. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, grapefruit, and antacid medicines. FILSPARI and other medicines may affect how each other works and cause side effects. Do not start any new medicine until you check with your healthcare provider. Especially tell your healthcare provider if you take: nonsteroidal anti-inflammatory drugs (NSAIDs), potassium-containing medicines, potassium supplements or salt substitutes containing potassium, or blood pressure medicines.

FILSPARI can cause serious side effects, including liver problems, serious birth defects, low blood pressure, worsening of kidney function, increased potassium in your blood, and fluid retention. Tell your healthcare provider if you feel dizzy, light-headed, faint, or have any unusual weight gain or swelling of your ankles or legs as these can be signs of serious side effects while taking FILSPARI. Your healthcare provider will check your kidney function and potassium blood level during treatment with FILSPARI. The most common side effects include swelling of the hands, legs, ankles and feet (peripheral edema), dizziness, and low red blood cells (anemia). These are not all the possible side effects of FILSPARI. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088 or <u>www.fda.gov/medwatch</u>. You may also report side effects to Travere Therapeutics at 1-877-659-5518.

Please see additional Important Safety Information throughout this guide. Please also see the full <u>Prescribing Information</u>, including serious side effects, and the <u>Medication Guide</u>.

